UNIVERSITI MALAYA

Policy and **Procedure** on **Laboratory Biosafety** and **Biosecurity**

Institutional Biosafety and Biosecurity Committee
Universiti Malaya

Second Edition, 2026

UNIVERSITI MALAYA

JAWATANKUASA KEINSTITUSIAN BIOKESELAMATAN DAN BIOSEKURITI
Institutional Biosafety and Biosecurity Committee

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FOREWORD BY THE DEPUTY VICE CHANCELLOR (RESEARCH & INNOVATION)

The handling of biological materials in laboratory environments is essential for advancing scientific research, education and innovation. However, such activities also present inherent risks that must be carefully managed to ensure the safety and security of laboratory personnel, the surrounding community and the environment. These risks include biosafety concerns, such as accidental exposure or unintentional release of infectious agents, as well as biosecurity threats involving the theft, misuse or deliberate release of biological materials.

Recognising these challenges, Universiti Malaya has strengthened its commitment to establishing a comprehensive framework for laboratory biosafety and biosecurity. The Policy and Procedure on Laboratory Biosafety and Biosecurity serves as an institutional guideline to support effective biological risk management across all relevant laboratory activities within the University.

This policy outlines the main principles, roles, and procedures for the safe handling, storage, and management of biological materials. It encourages risk- and evidence-based practices to ensure safety measures remain relevant and adaptable to scientific and technological changes.

Furthermore, the policy highlights the importance of compliance with applicable national regulations and internationally recognised biosafety and biosecurity. In doing so, Universiti Malaya aims to foster a responsible research environment that balances scientific advancement with the need to safeguard public health, security and environmental protection.

Professor Ir. Dr. Kaharudin Dimyati
Deputy Vice Chancellor (Research & Innovation)
Universiti Malaya

PREFACE BY THE CHAIR OF THE INSTITUTIONAL BIOSAFETY & BIOSECURITY COMMITTEE (IBBC)

Universiti Malaya remains committed to promoting a safe, secure and responsible research environment that supports excellence in scientific discovery and innovation. As laboratories continue to play a critical role in advancing knowledge in the life sciences, it is essential that all activities involving biological materials are conducted in accordance with robust biosafety and biosecurity principles.

The Policy and Procedure on Laboratory Biosafety and Biosecurity represents Universiti Malaya's strategic commitment to strengthening biological risk management across the institution. This policy provides a structured framework to guide faculties, research institutes and laboratories in implementing appropriate safety and security measures when handling biological agents, toxins and other potentially hazardous biological materials.

By integrating biosafety and biosecurity into laboratory management systems, the University seeks to ensure that risks associated with biological research and laboratory work are systematically identified, assessed and mitigated. This includes promoting a strong culture of safety, enhancing competency through continuous training, and ensuring effective reporting and response mechanisms for laboratory incidents.

In light of the rapidly evolving landscape of biological threats, emerging infectious diseases and advancements in biotechnology, it is crucial that our policies remain responsive and adaptable. This policy therefore also addresses emerging concerns related to the misuse of life sciences research and the responsible conduct of research involving biological materials.

The successful implementation of this policy requires the collective commitment of all members of the Universiti Malaya community, including researchers, laboratory personnel, students and administrators. Through shared responsibility and adherence to best practices, we can ensure that our laboratories remain safe, secure and conducive environments for innovation and scientific advancement.

Associate Professor Dr. Cindy Teh Shuan Ju
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UNIVERSITI MALAYA POLICY AND PROCEDURE ON LABORATORY BIOSAFETY AND BIOSECURITY

1. INTRODUCTION

Working with biological materials entails inherent risks that must be carefully managed to ensure safety and security. These risks include biosafety concerns, such as accidental exposure or unintentional release, as well as biosecurity threats, including theft, misuse or deliberate release of biological materials. This underscores the critical need for a robust biosafety and biosecurity framework as a cornerstone of comprehensive biological risk management.

Laboratory biosafety and biosecurity are fundamental to protecting laboratory personnel, the broader community and the environment from accidental exposure or release of infectious agents. The safe handling of pathogens, microbial toxins and other biological materials is essential to addressing the evolving threats posed by infectious diseases. By adopting a risk- and evidence-based approach, these practices remain relevant, proportionate and effective across different contexts.

Key measures include the establishment of standard operating procedures (SOPs), adherence to good microbiological practices, continuous training and prompt incident reporting with corrective actions. These initiatives not only mitigate risks but also play a vital role in advancing prevention, detection and control strategies, ultimately contributing to the development of new vaccines and therapeutics.

This policy aims to integrate biosafety and biosecurity into laboratory management systems for Universiti Malaya. They are designed to be adaptable to a wide range of activities, ensuring their relevance and applicability. In light of the rapidly changing landscape of biological threats and technological advancements, the policy also addresses emerging risks such as the misuse of life sciences research and innovative biotechnologies.

Additionally, the policy emphasises compliance with national and international regulations, striving to establish sustainable laboratory environments that balance scientific progress with the need to minimize associated risks.

2. LIST OF ABBREVIATIONS

BSO	Biosafety Officer
CWA	CEN Workshop Agreement
DVC (R&I)	Deputy Vice-Chancellor (Research & Innovation)
GLP	Good Laboratory Practice
GMPP	Good Microbiological Practice and Procedure
ERP	Emergency Response Plan
HOD	Head of Department
IBBC	Institutional Biosafety and Biosecurity Committee
MTA	Material Transfer Agreement
NOI	Notice of Intent
NoT	Notice of Transfer
OSHEC	Occupational Safety & Health and Environment Centre
PI	Principal Investigator
SOP	Standard Operating Procedure
UM	Universiti Malaya

VC	Vice Chancellor
WHO	World Health Organization
PTj	Responsible Centre

3. SCOPE

This document takes a risk- and evidence-based approach to biosafety and biosecurity for the handling, managing and containing biological materials in all forms and sizes of laboratories and work areas within and outside UM in compliance with institutional and regulatory requirements. This document serves as a reference for personnel implementing biosafety and biosecurity measures related to biological risk management and Good Microbiological Practices and Procedures (GMPP).

4. PURPOSE

This document formalises the obligation of Universiti Malaya (UM), the UM Institutional Biosafety and Biosecurity Committee (IBBC) and personnel involved in the handling, management and containment of biological materials in compliance with national and international biosafety and biosecurity requirements.

5. DEFINITIONS

1) Activities - research, teaching and services that involve handling, management, and containment of biological materials.

2) Accident - an inadvertent occurrence that results in actual harm such as infection, illness, injury in humans or contamination of the environment (adapted from Laboratory Biosafety Manual, fourth edition, 2020).

3) Biological agents - any microbiological entity, cellular or non-cellular, naturally occurring or engineered, capable of replication or of transferring genetic material; including bacteria, fungi, viruses, viroids, prions, endo- and ectoparasites that may be able to provoke infection, allergy, toxicity or other adverse effects in humans, animals or plants. Biological agents cover commonly used terms such as

pathogens, quarantine microorganisms and microorganisms of dual-use potential (adapted from ISO 35001:2019 Biorisk Management for Laboratories and Other Related Organisations).

4) Biological materials - any material composed of, containing or that may contain biological agents and/or their harmful products such as toxins and allergens. Biological materials may be blood, secretions or tissues of human or animal origin. Other biological materials include debris organic material from nature, culture or preservation media and/or cell cultures from human, animal and plants. Additionally, animals and plants or parts thereof handled in relevant laboratories that may contain biological agents or toxins, or biological agent vectors such as arthropods, nematodes and mites are also considered biological materials (adapted from ISO 35001:2019 Biorisk Management for Laboratories and Other Related Organisations).

5) Biosafety - containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release (adapted from Laboratory Biosafety Manual, fourth edition, 2020).

6) Biosecurity - policies, principles, technologies and practices implemented to ensure the protection, control and accountability of biological material, technology and information as well as the equipment, methods, skills and data related to their handling. Biosecurity aims to prevent intentional or accidental unauthorised access to, and loss, theft, misuse, diversion or release or even weaponisation of such commodities (adapted from Laboratory Biosecurity Guidance, second edition, 2024).

7) Containment - the combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological agents (adapted from Laboratory Biosafety Manual, fourth edition, 2020).

8) Facility - operational unit and associated buildings and equipment used to manage biological agents and toxins.

   NOTE 1: This includes the laboratory, together with the supporting infrastructure, equipment and services including ancillary rooms such as airlocks, changing rooms, sterilizing room and storage rooms (adapted from Laboratory Biorisk Management CWA 15793:2011, European Committee for Standardization, ICS 07.100.0).

9) Good Microbiological Practice and Procedure (GMPP) - a basic laboratory code of practice applicable to all types of laboratory activities with biological agents, including general behaviours and aseptic techniques that should always be observed in the laboratory. This code serves to protect laboratory personnel and the community from infection, prevents contamination of the environment and provides protection for the work materials in use (adapted from: Laboratory Biosafety Manual, fourth edition, 2020).

10) Good Laboratory Practice (GLP) - a quality system concerned with the organizational process and the conditions, under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported (adapted from Handbook: Good Laboratory Practice (GLP) - Quality Practices for Regulated Non-Clinical Research and Development, second edition, 2009).

11) High-consequence material - a biological agent, biological material or technology and the information that can cause, direct or indirect, disease or other significant harmful effects in humans, animals, plants and/or the environment (adapted from Laboratory Biosecurity Guidance, second edition, 2024).

12) High-consequence research - research with intended benefits that uses or creates material, technology or information that could cause significant harmful effects on humans or their social systems (such as their economy), animals, plants and/or the environment (adapted from Laboratory Biosecurity Guidance, second edition, 2024).

13) Incidents - an occurrence that has the potential to, or results in, the exposure of laboratory personnel to biological agents and/or their release into the environment that may or may not lead to actual harm (adapted from Laboratory Biosafety Manual, fourth edition, 2020).

14) Non-UM PI - Researchers who are not employed or affiliated with UM.
15) Notice of Intent (NOI) - an application for approval prior to the commencement of the proposed activity.
16) Principal Investigator (PI) - the lead scientist who takes direct responsibility for a project's technical and/or scientific direction, the relevant course coordinator and the service laboratory director.
17) Personnel - any individuals involved in the handling, management and containment of biological materials either in the field of research, teaching and/or services (including UM and non-UM staff/students).
18) Record - a document stating results achieved or providing evidence of activities performed (adapted from Occupational Health and Safety Management System (OHSMS) certification ISO 45001:2018).
19) Risk assessment - a systematic process of gathering information and evaluating the likelihood and consequences of exposure to or release of workplace hazard(s) and determining the appropriate risk control measures to reduce the risk to an acceptable risk (adapted from Laboratory Biosafety Manual, fourth edition, 2020).
20) Toxin/Allergen - substance produced by plants, animals, protists, fungi, bacteria or viruses, which in small or moderate amounts produces an adverse effect in humans, animals or plants (adapted from ISO 35001:2019 Biorisk Management for Laboratories and Other Related Organizations).

6. ROLES AND RESPONSIBILITIES

6.1. **Universiti Malaya (UM) is to**

6.1.1. establish the IBBC;

6.1.2. appoint Chairperson, Biosafety Officer (BSO), Members and Coordinators;

6.1.3. ensure that the resources needed for the biorisk management programs are available.

6.2. **Institutional Biosafety and Biosecurity Committee (IBBC)**

The IBBC is a UM entity responsible for overseeing all activities involving the handling, management and containment of biological materials.

6.2.1. Responsibilities of the IBBC

a) Report and advise the Vice Chancellor (VC) through the Deputy Vice Chancellor (Research and Innovation) (DVC (R&I)) and/or Occupational Safety, Health and Environment Centre (OSHEC).

b) Review the submitted Notice of Intent (NOI) for activities involving the use of biological materials for compliance with updated national and international policies, laws, regulations and guidelines related to biosafety and biosecurity matters.

c) Notify the Principal Investigator (PI) of the outcome of the submitted NOI.

d) Periodically review the compliance of all approved activities involving the use of biological materials.

e) Submit periodic reports on activities involving biological materials to the VC and any other relevant agencies as required.

f) In cases of non-compliance, fraud or integrity violations, IBBC will suspend or revoke the approval. IBBC will issue a formal letter to the PI, and the matter will be referred to the relevant parties for further action.

g) Coordinate with the PI and relevant parties on incidents, accidents, corrective and preventive actions to minimize future occurrences.

h) Conduct biosafety and biosecurity training programs.

i) Maintain all records for a minimum of seven (7) years.

j) Periodically review biosafety and biosecurity policies and recommend amendments when necessary.

k) Maintain compliance with updated national and international obligations and legal frameworks related to biosafety and biosecurity.

6.3. **Chairperson of the IBBC**

The Chairperson shall be appointed by the VC from among the IBBC members for a renewable term of at least two (2) years with a maximum of three (3) consecutive terms.

6.3.1. Qualifications

a) The Chairperson shall be an academic staff of UM.
b) The Chairperson shall have experience and expertise in working with biological materials.

6.3.2. Responsibilities

a) Chair the IBBC meetings.
b) Approve meeting minutes and agenda before it is shared with the committee members.
c) Nominate candidate(s) to the VC for appointment as BSO.
d) Nominate candidates to the DVC (R&I) for appointment as committee members.

6.4. **Biosafety Officer (BSO)**

The BSO shall be appointed by the VC for a renewable term of at least two (2) years.

6.4.1. Qualifications

a) The BSO shall have at least a bachelor's degree in biological science or a relevant field.
b) The BSO shall have experience and training in biosafety and biosecurity, including biorisk management.

6.4.2. Responsibilities

a) Serves as the Executive Secretary of the IBBC.
b) Prepare and review meeting minutes and agendas before submitting them to the Chairperson of the IBBC for approval, prior to distribution to committee members.

c) Report on non-compliance to policy and guidelines and violation of any rule and regulation to the IBBC.
d) Initiate an investigation of any biosafety and biosecurity-related incidents, accidents, illnesses or breaches and report to the IBBC.

6.5. **Members of the IBBC**

The DVC (R&I) shall appoint at least three (3) IBBC members for a renewable term of no less than two (2) years.

6.5.1. Qualifications

IBBC members shall have experience and training in biosafety and biosecurity, including biorisk management.

6.5.2. Membership

May include, but not limited to academics, scientists, researchers, veterinarians, legal officers, representatives of technical and laboratory management.

6.5.3. Responsibilities

a) Attend at least 80% of IBBC meetings during a calendar year.
b) Review all NOI applications, amendments and extensions.
c) To declare a conflict of interest in the review of NOI (refer to Section 6.10).
d) Support the IBBC in biosafety and biosecurity training.

6.6. **IBBC Coordinator**

The DVC (R&I) shall appoint the IBBC coordinator for a renewable term of at least two (2) years.

6.6.1. Qualifications

IBBC coordinators shall have basic knowledge of research and laboratory management.

6.6.2. Responsibilities

a) Serve as the contact person at respective PTj for NOI applications.
b) Assist the IBBC in conducting pre- and post-approval inspection and monitoring of approved activities at respective PTj.

6.7. **Principal Investigators (PI)**

6.7.1. Responsibilities

PIs who handle biological material in their research, teaching or services shall

a) submit the Preliminary Assessment Form to the IBBC for any work involving biological materials;
b) if required, submit the NOI application to the IBBC;
c) cooperate with the IBBC requests for inspections, NOI reviews additional documentation or inspections;
d) ensure that all personnel are trained in biosafety and biosecurity protocols;
e) implement corrective actions or safety recommendations provided by the IBBC;
f) report any incidents, accidents, illnesses, or breaches of biosafety and biosecurity to the IBBC;
g) notify the IBBC if there is any occurrence of adverse events following the activities involving biological materials;
h) comply with national and international obligations and legal frameworks on activities involving handling, management and containment of biological materials;
i) maintain records of all procedures and materials used for at least seven (7) years.

6.7.2. The responsibilities above are applicable to both UM and non-UM PIs.

6.8. **Researchers and Students**

6.8.1. Responsibilities

Personnel who are conducting activities involving biological materials shall follow all biosafety and biosecurity protocols as outlined by the PI and approved by the IBBC, including

a) participating in biosafety and biosecurity training and completing all training required for their specific roles and tasks;
b) adhering to established SOP for the handling, managing, and containment of biological materials;
c) reporting any incidents, accidents or potential biosafety and biosecurity risks to PI and/or relevant parties;
d) maintaining records of all activities involving biological materials;
e) complying with national and international obligations and legal frameworks that govern such activities.

6.9. **Meetings**

6.9.1. The IBBC shall meet at least eight (8) times or more frequently as necessary in a calendar year.

6.9.2. A quorum of at least fifty per cent (50%) of members (with the mandatory attendance of the Chairperson/Acting Chairperson and BSO) must be present during the IBBC meeting for decisions to be made.

6.10. **Conflict of Interest**

6.10.1. IBBC members must disclose any potential conflicts of interest related to the NOI under review. Any IBBC member who declares a conflict of interest shall not participate in the review and approval of the respective NOI.

6.10.2. Minutes of the meeting must record details of any IBBC member who has declared a conflict of interest.

7. SUBMISSION OF PRELIMINARY ASSESSMENT FORM AND NOI TO THE IBBC AND THE REVIEW PROCESS

7.1. Submission of Preliminary Assessment Form

7.1.1. PI shall notify and obtain approval from the IBBC through the submission of the Preliminary Assessment Form for all activities that

a) involve the handling, management and containment of biological materials;

b) are conducted by either UM and non-UM staff/student or a combination of both;

c) are conducted within or outside the premises of UM.

7.1.2. Upon reviewing the Preliminary Assessment Form, the IBBC shall notify the applicant within seven (7) working days of the decision whether a Notice of Intent (NOI) submission is required or exempted.

7.2. Submission of an NOI

7.2.1. Upon the notification that an NOI is required, the PI shall submit the NOI Form and relevant documents to the IBBC.

7.2.2. The applicant and all personnel involved in activities involving biological materials must complete a minimum of eight (8) hours of training on Biosafety and Biosecurity. They must demonstrate completion of this training by providing a valid certificate of completion.

7.2.3. Only complete submission of NOI documents (before the cut-off date) will be tabled for review meeting.

Note 1: For high-consequence research activities, PIs shall provide proof of their job-specific training or sufficient experience in biosafety and biosecurity to the IBBC.

7.3. NOI Review Process

7.3.1. Upon submission, the BSO/IBBC Coordinator will ensure that all required documents are present. In instances where documents are lacking, the applicant will be notified, and the application must be resubmitted along with the required documents.

7.3.2. Each application will be assigned to at least one (1) IBBC member for primary review.

7.3.3. IBBC members will review all NOI submissions in an IBBC meeting and the PI may be requested to present their project during this time. If necessary, a pre-approval laboratory inspection may be conducted.

7.3.4. Approval of the NOI will be granted only when the majority of IBBC members determine that the proposed activities, personnel and biosafety and biosecurity requirements meet the IBBC requirements.

7.3.5. PIs shall be informed in writing of the NOI review outcome within thirty (30) working days after the review meeting. All communications must be recorded and documented by the BSO and the committee member.

7.4. **Outcomes of NOI Review**

7.4.1. Approved - this status is given to an NOI that satisfactorily addresses all issues pertaining to biosafety and biosecurity. No additional amendments or changes to the NOI are required. The approved NOI is valid for a maximum of three (3) years unless otherwise specified in the approval letter by the IBBC.

7.4.2. Approved pending minor modifications - minor revisions are required to the NOI. Work under the NOI can only be initiated when the PI addresses all issues raised by the IBBC in the latest review outcome and an “Approved” status is granted for the NOI by the IBBC.

7.4.3. Deferred - the NOI is deferred when consultation from an external body is required due to the IBBC members’ limited experience and/or expertise in the proposed field of study and/or technical procedures involved in the study.

7.4.4. Withhold approval - the NOI is withheld if it has not adequately addressed all issues pertaining to the applicable principles of biosafety and biosecurity.

7.4.5. Revision and resubmission of the NOI shall be made within three (3) months of the latest review outcome; otherwise, the PI must submit a new NOI.

7.5. **Amendments to approved NOI**

7.5.1. PIs shall submit to IBBC through the submission of the Amendment Form if there are any amendments to their approved NOI.

7.5.2. Modifications that require submitting an amendment application include but are not limited to changes in the biological materials used, experimental design, personnel, location, or any changes that may increase the Risk Group of the biological materials or containment measures.

7.5.3. The amendment(s) must be reviewed and Approved by the IBBC before any work under the NOI can be continued. PIs shall be informed in writing of the NOI amendment outcome within thirty (30) working days after the review meeting.

7.5.4. All communications must be recorded and documented by the BSO and the committee members.

7.6. **Extension of Approved NOI**

7.6.1. PIs are required to submit the application for NOI extension at least three (3) months before the expiry date through the submission of the Extension Form.

7.6.2. NOI extension applications will be reviewed by the IBBC before it is approved. PIs shall be informed in writing of the NOI extension outcome within thirty (30) working days after the review meeting. All communications must be recorded and documented by the BSO and the committee members.

7.6.3. The maximum extension period is limited to one (1) year.

7.7. **Post-Approval Monitoring**

7.7.1. The IBBC may inspect the laboratories and facilities to ensure biosafety and biosecurity compliance according to national and international obligations and legal frameworks that govern such activities.

7.7.2. The inspection date will be communicated to the PI in advance. Any non-compliance identified will lead to the immediate suspension or revocation of the approval. In the event of a suspension or revocation of the approval, the PI must immediately halt all activities covered by the approval and implement corrective actions as directed by the IBBC.

7.7.3. The IBBC members performing the inspection will prepare a report of the findings to be submitted to both the IBBC and the PI concerned.

7.8. **Final Report**

7.8.1. The PI shall submit a final report to the IBBC within ninety (90) days of the project end date.

7.8.2. Failure to submit the report within the designated period may result in the withholding of new approvals.

7.8.3. The submission flow for the Preliminary Assessment Form and NOI to the IBBC, along with the review process, is outlined in Attachment A (Figure 1: Flow Process on IBBC Submission and Review Process).

8. TRANSFER AND PROCUREMENT OF BIOLOGICAL MATERIALS

8.1. **Transfer of Biological Materials Within UM**

Transfer of biological materials within the University campus must comply with the following

8.1.1. A Notice of Transfer (NoT) must be signed by the Head of Department (HOD), with delegation of authority from the Head of PTj, for any transfers within UM. A copy of the signed NoT must be submitted to the IBBC for record-keeping.

8.1.2. Packaging must comply with national and international obligations and legal frameworks.

8.2. **Transfer of Biological Materials Outside of UM**

All transportation of biological materials out of UM must comply with the following

8.2.1. The Material Transfer Agreement (MTA) must be signed by the VC and a copy must be submitted to the IBBC for record keeping.

8.2.2. All packaging, transfer, transport, and shipping of biological materials must comply with national and international obligations and legal frameworks.

8.3. **Procurement of biological materials**

8.3.1. The NoT required for the import of biological materials shall be endorsed by IBBC.

8.3.2. The nature, quantity and volume of the biological materials shall be clearly stated in the NoT.

9. BIOHAZARDOUS WASTE MANAGEMENT

9.1. All biohazardous waste is to be considered as “scheduled waste” and shall be handled and disposed of in a manner consistent with UM procedures, national and international regulations.

9.2. All personnel involved in biohazardous waste management must receive training on relevant legal regulations, waste classifications, safe handling procedures, and emergency response protocols.

10. EMERGENCY RESPONSE PLAN (ERP)

10.1. Written emergency response plans for all credible and foreseeable emergency scenarios shall be made available to all personnel.

10.2. All personnel must receive training on the emergency response plans.

11. LOSS OR THEFT OF BIOLOGICAL MATERIALS OR DATA

11.1. All personnel shall ensure that biosecurity risks are identified and appropriate control measures are implemented.

11.2. Any loss or theft of biological materials or data must be reported to the IBBC.

11.3. An updated inventory of all biological materials or data must be properly maintained.

12. RECORD KEEPING

12.1. IBBC shall maintain the security and confidentiality of data records including registrations, documents, laboratory personnel details and copies of all documented correspondence.

12.2. All records must be kept for seven (7) years as required by the IBBC and regulatory bodies.

13. RELEVANT DOCUMENTS AND REFERENCES

1) Laboratory Biosafety Manual, Fourth Edition, World Health Organization, Geneva, 2020.
2) Laboratory Biosecurity Guidance, World Health Organization, September 2024
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15) Policies and Procedures of the Emory University Institutional Biosafety Committee, Version 2, Environmental Health and Safety Office, Emory University, March 12, 2014.
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Attachment A

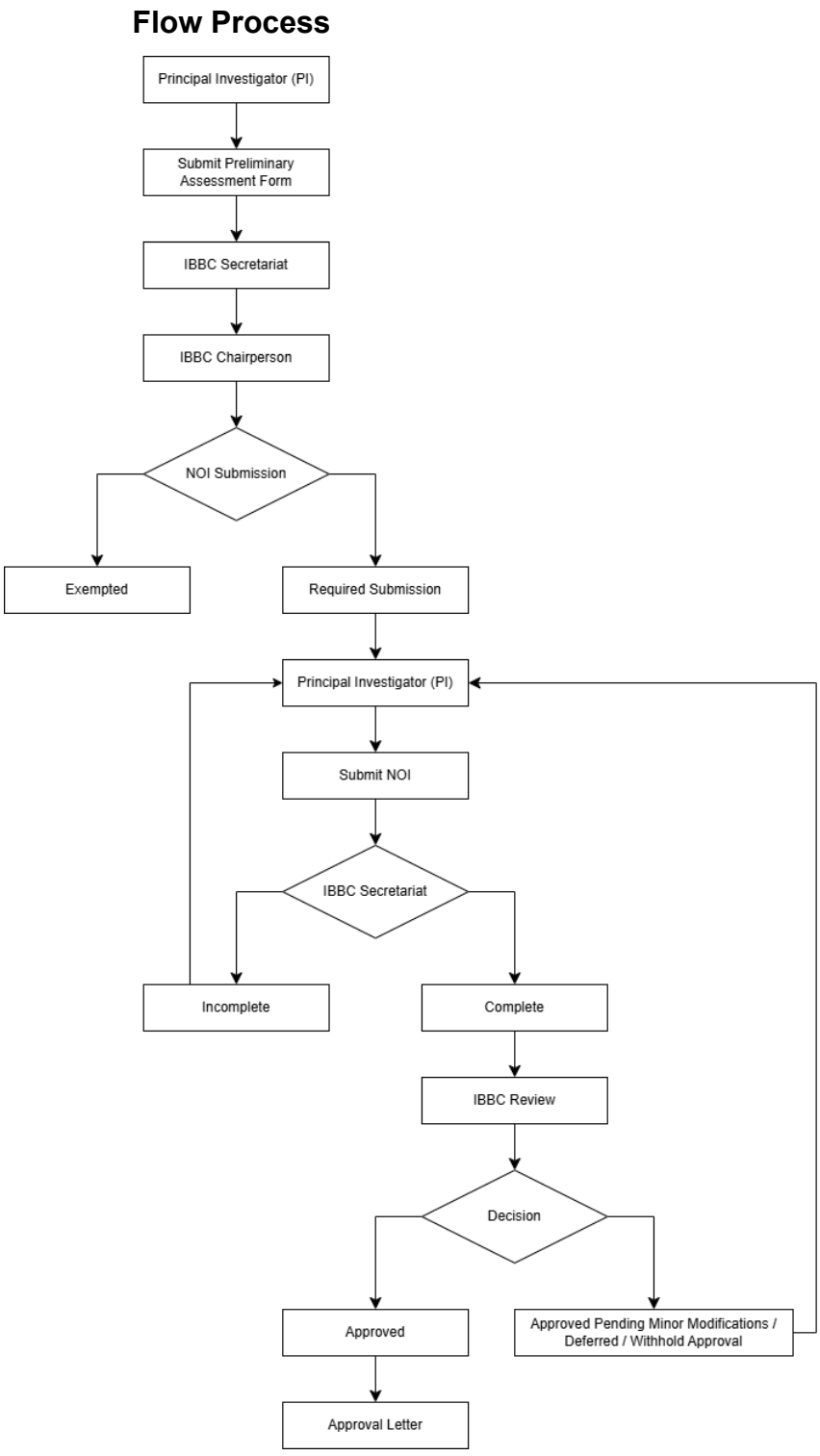

Figure 1: Flow Process for IBBC Submission and Review Process